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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/254,344 | 09/03/1999 | YOSHIIHIDE HAYASHIZAKI | 024705-077 | 6838 |

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/254,344

Applicant(s)

HAYASHIZAKI ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-17 is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Applicants amendment of the specification and cancellation of claims 4, 5, 26 and 27, Paper No. 25, 3/18/2003, is acknowledged. Claims 11-23, are still at issue and are present for examination.

Specification

The disclosure is objected to because of the following informalities:

On page 7 of the specification under the Brief Description of the Drawings for Figure 4 it states that Figure 4 (SEQ ID NOs: 3-6) shows the alignment of amino acid sequences of the currently reported phage-derived RNA polymerases. However upon inspection the sequences of SEQ ID NOs: 3-6 do not appear to agree with the residue numbering used on the left side of the figure for each of SEQ ID NOs: 3-6. Further illustrating this confusion can be seen in the fact that the sequence of SEQ ID NO: 3 (T7 polymerase) is listed as 854 amino acids in length and the sequence which corresponds to the T7 polymerase of Figure 4 is 883 amino acids in length. Similar to above, SEQ ID NO: 4 (T3 polymerase) is listed as 852 amino acids in length and the sequence which corresponds to the T3 polymerase of Figure 4 is 884 amino acids in length. Similar to above, SEQ ID NO: 5 (K11 polymerase) is listed as 876 amino acids in length and the sequence which corresponds to the K11 polymerase of Figure 4 is 906 amino acids in length. Similar to above, SEQ ID NO: 6 (K11 polymerase) is listed as 841 amino acids in length and the sequence which corresponds to the K11 polymerase of Figure 4 is 875 amino acids in length.

Similarly to the confusion for Figure 4 as described above, Figures 3, 6 7, is also confusing.

It is pointed out to applicants that the drawings, description of the drawings and other parts of the specification such as sequences in the sequence listing, etc... should match, so as not to lead to confusion, as the claims are interpreted in light of the specification. Therefore, if the specification is confusing, it remains that the claims may be rendered confusing.

Appropriate correction is required.

Claim Objections

Claims 19 and 21 are objected to because of the following informalities:

Claims 19 and 21 each recite "...or deletion of amino acid other than the ...". This should be amended to recite "...or deletion of an amino acid other than the ...", in order to be consistent with the similar recitation in claim 12. For the purpose of advancing prosecution, this is how the claim is interpreted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18-23 are each indefinite in that they are each drawn to a RNA polymerase of T3, K11 and SP6 in which specific residues of specific SEQ ID NOs are mutated. Each of these references to the specific amino acid residues that are mutated are confusing in that they recite, for instance in the case of claim 18 (claim 19 dependent from), amino acid residue number 645 or 668 of SEQ ID NO: 14. It should be noted that this reference is confusing because SEQ ID NO: 14 is only 73 amino acid residues long and thus it is unclear to what applicants are referring when they recite amino acid residues 645 and 668 of SEQ ID NO: 14. Claims 20 (claim 21 dependent from) and 22 (claim 23 dependent from) are similarly confusing in that they refer to amino acid residues 664-669 and 690 of SEQ ID NO: 15 and amino acid residues 633-638 and 670 of SEQ ID NO: 16, respectively. SEQ ID NO: 15 and SEQ ID NO: 16 are 73 and 75 amino acids in length, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
May 27, 2003